

UNITED STATES DISTRICT COURT FOR THE  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION ) MDL No. 2804  
OPIATE LITIGATION )  
THIS DOCUMENT RELATES TO: ) Case No. 1:17-md-2804  
*Track One Cases* ) Judge Dan A. Polster  
)

REPLY IN SUPPORT OF HBC SERVICE COMPANY'S  
MOTION FOR SUMMARY JUDGMENT

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Plaintiffs’ opposition to HBC Service Company’s (“Giant Eagle”) motion for summary judgment is remarkable for what it does not do. That opposition offers no evidence that Giant Eagle distributed any opioids into Cuyahoga and Summit Counties (the “Counties”) that were diverted. It does not identify a single order that Giant Eagle shipped from its warehouse to its pharmacies that was suspicious under 21 C.F.R. § 1301.74. It does not offer any actual evidence (as lawyer argument does not count for summary judgment purposes) that Giant Eagle’s extensive SOM and other security measures did not comply with DEA regulations. It does not point to any fine or allegation by the DEA that Giant Eagle ever violated Section 1301.74. And perhaps most remarkably, Plaintiffs’ opposition fails to acknowledge what is plain to all—that, if the DEA determined during its many audits that Giant Eagle’s SOM program did not comply with its regulations, the DEA would have mentioned that to Giant Eagle.

Rather than offer counterevidence, Plaintiffs offer only excuses for their complete failure of proof against Giant Eagle. First, Plaintiffs ask this Court to believe that, despite relying heavily on expert testimony of purported non-compliance with the CSA against other Defendants in the bellwether cases, they can somehow get by without such testimony against Giant Eagle. But expert testimony on DEA regulatory compliance is essential to all claims asserted against all Defendants—including Giant Eagle. Whether an industry participant has complied with an arcane, ambiguous, and complex regulation like Section 1301.74 is, by definition, beyond the common knowledge and understanding of a lay juror. Even Plaintiffs acknowledged this unassailable proposition when, in opposing *Daubert* attacks on their DEA regulatory compliance experts, they told this Court that expert testimony regarding suspicious order monitoring is necessary to “assist the jury by providing important background and context on the complex regulatory scheme

applicable to opioid manufacturers and distributors, which is likely unfamiliar to a layperson.” Whitelaw Opp. at 13-14 (Dkt. 2189/2221).

Plaintiffs next try to excuse their lack of evidence by pointing to isolated incidents that occurred at Giant Eagle’s pharmacies. But the employee theft Plaintiffs identify occurred *outside of the Counties*. Plaintiffs’ other so-called evidence of pharmacy diversion is not evidence at all, but rather, a citation to *United States v. Eppinger*, 2012 WL 6930580 (N.D. Ohio Mar 13, 2012), an indictment of a drug dealer who used a stolen prescription pad to forge opioid prescriptions. Notably, the fraudulent prescriptions in Eppinger—like the prescriptions Plaintiffs erroneously identified during discovery—were for opioid products that Giant Eagle’s HBC warehouse *never distributed*. As Plaintiffs well know, they have targeted the HBC warehouse solely because it distributed a single opioid—HCPs—to Giant Eagle pharmacies in the Counties from November 2009 to October 2014.

Plaintiffs are, therefore, left with nothing to defeat Giant Eagle’s motion for summary judgment. As explained below, Giant Eagle is entitled to summary judgment not merely because it had a minuscule market share of prescription opioids sales (though it did), but rather, because there is no evidence that Giant Eagle did anything wrong. As Giant Eagle has said all along, Plaintiffs should have never pulled it into this lawsuit in the first place.

#### **I. The undisputed expert evidence shows that Giant Eagle fully complied with the CSA.**

Plaintiffs have proffered two SOM experts—James Rafalski and Seth Whitelaw—who opine that certain defendants’ SOM programs did not comply with DEA regulations. *See* Rafalski Rep. (Dkt. 1999-21/2000-22); Whitelaw Rep. (Dkt. 1999-25/2000-26).<sup>1</sup> Though Plaintiffs

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<sup>1</sup> *See also* Rafalski Tr. 680:9-13 (Dkt. 1969-19/1983-16) (explaining that his analysis looked at “whether or not there was a suspicious order system [for the defendants] that met the regulatory requirements and the maintenance of effective controls”); Whitelaw Tr. 483:13-23 (Dkt. 1972-67/1985-18) (“[W]hat I was looking at...are indicia of not having an effective [SOM] program.”).

presumably tried, they could not convince their experts to opine that Giant Eagle violated any DEA regulation. Rafalski and Whitelaw do not even mention Giant Eagle, let alone offer an opinion that its SOM program was deficient. That omission alone dooms Plaintiffs' claims against Giant Eagle.

When a "causal connection" is "beyond the common knowledge and understanding of the jury," as it most assuredly is here, "a plaintiff *must* present expert testimony." *Bailey v. United States*, 115 F. Supp. 3d 882, 891 (N.D. Ohio 2015) (emphasis added); *K&D Distrib., Ltd. v. Aston Grp., Inc.*, 354 F. Supp. 2d 761, 765-66 (N.D. Ohio 2005) (concluding that "expert testimony is required" because "[t]he conduct of a professional under these circumstances is not within the jury's general knowledge and experience"). Not surprisingly, Plaintiffs have conceded that the subject of compliance with the DEA's SOM regulations goes beyond the understanding of a lay juror. Hoping to defeat Defendants' *Daubert* attack on Seth Whitelaw, Plaintiffs argued that his assessment of Defendants' SOM programs would

assist the jury by providing important background and context on the *complex regulatory scheme* applicable to opioid manufacturers and distributors, which is likely *unfamiliar to a layperson*.... As an expert in the design, implementation and operation of compliance programs, Dr. Whitelaw provides valuable assistance to the jury in understanding the relevant standards applicable to Defendants' compliance and anti-diversion programs and the[ir] effectiveness....

Whitelaw Opp. at 13-14, (Dkt. 2189/2221) (emphasis added). If anything, expert testimony is even more critical when, as here, a defendant has proffered exculpatory expert testimony on the key liability and causation issues and the plaintiff has left that testimony unrebutted. *See* HBC Br. at 13 (Dkt. 1912/1923-1) (citing numerous cases).

Liability and causation are not the only issues requiring expert testimony. Because Plaintiffs' experts rely on one another, Rafalski and Whitelaw's failure to opine that Giant Eagle did not comply with the CSA severs any connection between Plaintiffs' damages experts and Giant

Eagle. Specifically, Rafalski and Whitelaw's silence leaves Plaintiffs with no way to tie Giant Eagle to any of the damages calculations proffered by Plaintiffs' experts Cutler, Gruber, and McGuire. Pls.' Opp. to Causation Mem. at 29 (Dkt. 2203/2204) (explaining how Cutler, Gruber, and McGuire relied on "important evidence" provided by Whitelaw, Rafalski, McCann, and Keller).<sup>2</sup> This evidentiary hole, by itself, also supports summary judgment in Giant Eagle's favor.

Though Plaintiffs were unable to offer expert testimony on the core issue of Giant Eagle's compliance with the CSA, Giant Eagle did offer such testimony. Giant Eagle experts Sandy Kinsey (a pharmacist and former pharmacy industry executive) and Matthew Greimel (a former DEA agent) both concluded that Giant Eagle fully complied with the CSA and related DEA regulations. HBC Br. at Ex. 2 (Dkt. 1912-4/1923-5) and Ex. 12 (Dkt. 1912-14/1923-15). So the record on this dispositive issue is not a close call—it is entirely one-sided in Giant Eagle's favor.

**II. The undisputed evidence shows that from day one Giant Eagle successfully operated a system to detect suspicious orders and prevent diversion.**

Plaintiffs have adopted a head-in-the-sand approach to the evidentiary record relating to Giant Eagle. With nothing to counter the evidence establishing that Giant Eagle's 2014 SOM policy replaced policies and procedures going back to the 2009 opening of HBC's controlled substance facility, Plaintiffs just ignore it. *Compare* Pls.' Opp. at 2, *with* Rogos Tr. 132:16-133:23 (Dkt. 1970-8/1984-1) (explaining that the 2014 policy was based on a pre-existing policy); Durr Tr. 64:19-69:21 (Dkt. 1961-20/1976-20). As the record makes clear, Giant Eagle's 2014 plan to seek accreditation as a Verified-Accredited Wholesale Distributor prompted it to create an entirely new set of written policies. Rogos Tr. 70:4-71:8 & 132:16-25. Because the predecessor policies

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<sup>2</sup> *See also id.* at 25-26 (explaining how Cutler's, Gruber's, and McGuire's "reports are inter-related"). Plaintiffs' incorporation of their causation brief is also a bluff. Other than inaccurately asserting that "HBC did not have a written SOM policy at all until 2014," *see infra*, the 84-page brief presents no evidence implicating Giant Eagle's distribution operation in the Counties.

were replaced, Giant Eagle did not formally archive them. Thus, though ignored by Plaintiffs, the undisputed record thoroughly undermines any speculation that the current absence of a written pre-2014 policy means that policies never existed. Ashley Tr. 252:5-12 (Dkt. 1956-7/1974-7) (testifying, as authorized by the DEA, that “how records [related to suspicious order monitoring] are kept” is up to the “discretion of distributors”); Rogos Tr. 132:16-133:17 (testifying that prior to 2014, the relevant policies were maintained in a notebook at the HBC facility).<sup>3</sup>

To the contrary, Giant Eagle’s witnesses have confirmed, through detailed testimony, that Giant Eagle had an effective SOM program that utilized controls at three different levels of the company from the moment it became a distributor of Schedule III controlled substances. At the corporate level, Giant Eagle executives actively monitored and investigated orders to prevent diversion.<sup>4</sup> To further guard against diversion, Giant Eagle’s “corporate team had full visibility of [HBC’s and each pharmacy’s] inventory at all times and could see if there was any fluctuation whatsoever.” Durr. Tr. 86:11-23 (Dkt. 1961-20/1976-20); *see also* Heiser Tr. 19:14-20:8 (Dkt. 1962-27/1978-7) (“We also had corporate oversight of both the stores and the warehouse. The warehouse had buyers that were monitoring from a human perspective the orders that were placed by the stores and also the orders that were placed to the manufacturers.”). While this corporate oversight was sufficient, Giant Eagle’s warehouse had strong controls over the intake, storage, and shipment of controlled substances to Giant Eagle’s pharmacies, including employees who closely

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<sup>3</sup> On top of that, the assumption behind Plaintiffs’ claim that Giant Eagle had no pre-2014 SOM policy—i.e., that all SOM policies must be in writing—has been rejected by the DEA itself. As the DEA’s Rule 30(b)(6) witness, Thomas Prevoznik explained that “[w]hat matters is do you have an effective means to safeguard against diversion” and conceded that the DEA regulations *do not* require “a written policy with respect to suspicious order monitoring.” Prevoznik Tr. 358:10-359:2 (Dkt. 1969-13/1983-10); *see also* 21 C.F.R. § 1301. The DEA regulations require that Giant Eagle operate an effective SOM system—not keep copies of outdated policies.

<sup>4</sup> Carlson Tr. 142:11-143:3 (Dkt. 1959-18/1975-18); Durr Tr. 92:12- 93:16 (Dkt. 1961-20/1976-20); Tsipakis Tr. 99:1-18 (Dkt. 1971-12/1985-4); Millward Tr. 100:11-101:2, 183:22-185:8 (Dkt. 1968-3/1981-20); *see also*, e.g., Defs.’ Resp. to MSJ re CSA Compliance Ex. 191 (Dkt. 2326/2387-16), Ex. 192 (Dkt. 2326/2387-17); Pls.’ Mot. re CSA Duties, Ex. 438 (Dkt. 1948-14/1967-14).

monitored controlled substance orders. Because the warehouse employees were “attuned to the normalcies” of orders coming from Giant Eagle pharmacies, if they saw any aberrations, they alerted their warehouse supervisors who would then investigate the order. Durr Tr. 90:8-91:7 & 92:12-93:8; HBC Br. at 3-5 (Dkt. 1912/1923-1); *see also* Pls.’ Mot. re CSA Duties, Ex. 439 (Dkt. 1948-15/1967-15).

As an additional safeguard against diversion, Giant Eagle’s pharmacies had strong controls over all medication inventories and rigidly adhered to controlled substance dispensing guidelines that required every pharmacist to review prescriptions for red flags that might indicate diversion. Giant Eagle also promised to support the judgment of any pharmacist who, “after performing required due diligence and in the exercise of his/her professional judgment...determines that a prescription should not be filled.” Defs.’ Resp. to MSJ re CSA Compliance, Ex. 193 (Dkt. 2326/2387-18) (at HBC\_MDL00180763); *see also*, e.g., *id.* at Ex. 194 (Dkt. 2326/2387-19); Ex. 195 (Dkt. 2326/2387-20).

But Giant Eagle’s anti-diversion controls did not end there. In 2013, Giant Eagle began implementing an entirely redundant SOM threshold system to further strengthen its existing controls against diversion. Giant Eagle instituted this threshold despite the fact that the DEA has *never* required such a system. *See* Prevoznik Tr. 108:23-109:4 (Dkt. 1969-12/1983-9) (agreeing that the “DEA did not require that a distributor use a particular calculation or algorithm to identify excessive purchases of controlled substances”); Wright Tr. 344:5-345:8 (Dkt. 1972-13/1985-25). Once implemented, Giant Eagle’s threshold system only confirmed what the company already knew—that its existing controls were highly effective at preventing diversion.

That all of these controls were effective cannot be, and has not been, reasonably contested. In audit after audit, the DEA never found Giant Eagle’s system to be deficient and, as such, never

fined or penalized Giant Eagle for failing to comply with the CSA. Prevoznik Tr. at 131:15-23 (Dkt. 1969-12/1983-9) (explaining that the DEA would tell registrants if their systems were not adequate). Nor did Giant Eagle’s ratio of controlled to non-controlled prescription sales ever come close to the level the DEA determined would suggest possible diversion. *Compare* Wright Tr. 260:4-18 (Dkt. 1972-12/1985-24) (confirming that “it was common for legitimate pharmacies to have a ratio of...20 percent of controlled to 80 percent noncontrolled”), *with* Am. Kinsey Rep. at ¶ 76 & Ex. H (Dkt. 1936-17/1939-17) (showing that Giant Eagle’s ratio was less than 10 percent). Finally, Giant Eagle’s market share of HCP prescriptions was significantly *less* than its market share for other controlled and non-controlled medications. Am. Kinsey Rep. at ¶ 78. In other words, Giant Eagle’s extensive controls against diversion were more than compliant with the CSA and effective in preventing diversion—something the DEA recognized when it audited Giant Eagle’s facilities.

**III. Plaintiffs offer nothing to rebut the ample evidence showing that Giant Eagle was not a substantial source of diversion in the Counties.**

Plaintiffs refuse to confront the evidence that Giant Eagle’s anti-diversion controls were effective. Instead, they falsely label Giant Eagle as a “major distributor of controlled substances” and then leap to the conclusion that Giant Eagle’s one percent market share in the Counties “allow[s] for a finding of public nuisance.” Pls.’ Opp. at 1, 9.<sup>5</sup> This is absurd. As Plaintiffs explain in their own brief, causation requires a showing that the alleged wrongful conduct had a “substantial rather than negligible” effect in causing a plaintiff’s harm. Restatement (Second) of Torts § 431, comment b (1965) (cited in Pls.’ Opp. Causation Mem. at 34 (Dkt. 2203/2204)).

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<sup>5</sup> To support this argument, Plaintiffs aggregate the number of individual pills and milliliters of liquid medication (calling them “units” or “dosage units”) over several years. But the term “dosage unit” is itself misleading, as the number of pills in a dose depends on the prescription and pill strength. Many doses consist of two or more pills and liquid measurements greater than one milliliter. By aggregating the smallest units possible, however, Plaintiffs are able to make the numbers sound misleadingly large to a layperson, despite the fact that the distributions are small when compared to the market.

Putting aside the complete lack of evidence that Giant Eagle did anything wrong, no matter how measured, Giant Eagle’s shipment of only one Schedule III drug (HCPs) to its own pharmacies for less than five years does not make it a substantial contributor to the opioid epidemic in the Counties. *See* Kinsey Tr. 214:7-10 (describing HBC’s market share in the Counties as “tiny. It’s minuscule”).

Plaintiffs also acknowledge that the prescriptions they identified during discovery do not relate to Giant Eagle’s *distribution* operations—the only operations at issue in this litigation. Pls.’ Opp. at 8; *see also* Op. and Order at 2 (Dkt. 1203) (“[T]he Retail Pharmacies may only be held liable as Distributors.”). To get around this problem, Plaintiffs now rely on *United States v. Eppinger*, 2012 WL 6930580, at ¶¶ 114, 116, 119 (N.D. Ohio Mar 13, 2012).<sup>6</sup> But this belated reliance on an indictment is also misplaced. *Eppinger* alleged the Defendant used a stolen prescription pad and physician information to fill forged prescriptions for Schedule II OxyContin and Percocet at Giant Eagle and other reputable pharmacies. But Giant Eagle’s HBC warehouse only distributed one product relevant to this litigation: HCPs. HBC Br. at 1-3 (Dkt. 1912/1923-1). It therefore did not even distribute the OxyContin or Percocet in question.<sup>7</sup>

## CONCLUSION

Plaintiffs’ failure to offer any proof that Giant Eagle did anything wrong simplifies the Court’s decision. Summary judgment must be granted in Giant Eagle’s favor.

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<sup>6</sup> Plaintiffs also reference a State Board of Pharmacy settlement, but fail to mention that it relates to a store that is not in the Counties. Thus, even if Plaintiffs could connect the isolated incidents of theft at Pharmacy No. 4098 to a suspicious order from the HBC warehouse (which they cannot), the resulting theft would still be unrelated to any injury or harm in the Plaintiff jurisdictions. In a separate brief, Plaintiffs have also conceded that “systems [to] prevent theft... have nothing to do with the identification and evaluation of suspicious orders” and “nothing to do with this litigation.” Pls.’ Mem. re Walmart’s MSJ at 8 (Dkt. 2218/2420).

<sup>7</sup> In any event, allegations from a pleading in another case do not constitute competent evidence in this case.

Dated: August 16, 2019

Respectfully submitted,

/s/ Robert M. Barnes

Robert M. Barnes

rbarnes@marcus-shapira.com

Scott D. Livingston

livingston@marcus-shapira.com

Joshua A. Kobrin

kobrin@marcus-shapira.com

MARCUS & SHAPIRA LLP

35th Floor, One Oxford Centre

301 Grant Street

Pittsburgh, PA 15219

Telephone: (412) 471-3490

Facsimile: (412) 391-8758

*Counsel for Defendant HBC Service*

*Company*

**CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1(f)**

Pursuant to Local Rule 7.1(f), I hereby certify that this Court has ordered that Defendants' summary judgement reply brief are subject to the limitations set forth in the Court's *Order Regarding Pretrial Motion for "Track One" Trial* (Dkt. No. 1653) at 3-4. The foregoing Reply, in coordination with Defendants' other Track One summary judgment filings, is in compliance with that Order.

Dated: August 16, 2019

Respectfully submitted,

/s/ Robert M. Barnes

Robert M. Barnes